Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12713

0 - FRONT

Form Approved: OMB No 0910-0291 Expires: 12/31/94
See OMB statement on reverse

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM CFSAN

For VOLUNTARY reporting by health professionals of adverse events and product problems

Page ___ of ___

FDA Use Only

Triage unit sequence # 7594 #2713

A. Patient information

1 Patient identifier [redacted] In confidence

2 Age at time of event: 64 or Date of birth [redacted]

3 Sex [✓] female [ ] male

4 Weight 230 lbs or ___ kgs

B. Adverse event or product problem

1. [✓] Adverse event and/or [✓] Product problem (e g , defects/malfunctions)

2 Outcomes attributed to adverse event (check all that apply)

- [ ] death ___ (mo/day/yr)
- [✓] life-threatening
- [✓] hospitalization – initial or prolonged
- [✓] disability
- [ ] congenital anomaly
- [✓] required intervention to prevent permanent impairment/damage
- [ ] other:

3 Date of event (mo/day/yr) 11-26-97

4 Date of this report (mo/day/yr) 1-9-98

5 Describe event or problem

Patient had a fairly extensive stroke. Although she had had a TIA a year prior, the Doctor felt an aspirin & blood pressure control was sufficient treatment. Several weeks before stroke, patient began a diet regimen on "Fit America" which entailed the taking of pills containing Ephedrine. The Family has retained sample of product available to FDA.

6 Relevant tests/laboratory data, including dates

N/A

7. Other relevant history, including preexisting medical conditions (e g , allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc)

Patient had well-controlled hyper-tension a cardiac history of palpatations. Patient is 64 year old active woman - non smoker

C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler, if known)

#1 Fit America - Natural Weight Control Aid - for Fit America, Inc., Deerfield Beach, FlA 33441

#2

2 Dose, frequency & route used

#1 Up to 5 capsules /day Each pill = 470 mg Ephedra Sinica

#2 Ma Huang standardized 1.4% ex.

3 Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 9/97 – 11-26-97

#2

4 Diagnosis for use (indication)

#1 Weight Loss

#2

5. Event abated after use stopped or dose reduced

#1 [ ] yes [ ] no [✓] doesn't apply

#2 [ ] yes [ ] no [ ] doesn't apply

6 Lot # (if known)

#1 251702

#2

7 Exp. date (if known)

#1 09/99

#2

8 Event reappeared after reintroduction

#1 [ ] yes [ ] no [✓] doesn't apply

#2 [ ] yes [ ] no [ ] doesn't apply

9 NDC # (for product problems only)

10 Concomitant medical products and therapy dates (exclude treatment of event)

Dynacirc 2 pills / 5 Mg
Propranolol 80 Mg
1 Asprin

D. Suspect medical device

1 Brand name

2 Type of device

RECEIVED JAN 16 1998

3 Manufacturer name & address

4 Operator of device

- [ ] health professional
- [ ] lay user/patient
- [ ] other

5 Expiration date (mo/day/yr)

6 model #

catalog #

serial # JAN 15 1998

lot # MEDWATCH CTU

other #

7 If implanted, give date (mo/day/yr)

8 If explanted, give date (mo/day/yr)

9 Device available for evaluation? (Do not send to FDA)

[ ] yes [ ] no [ ] returned to manufacturer on ___ (mo/day/yr)

10 Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1 Name, address & phone #

[redacted]

000001

2 Health professional? [ ] yes [✓] no

3 Occupation Neighborhood Re-development

4 Also reported to

- [ ] manufacturer
- [ ] user facility
- [ ] distributor

5 If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. [ ]

FDA

Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

ADVICE ABOUT VOLUNTARY REPORTING

Report experiences with:

- medications (drugs or biologics)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- other products regulated by FDA

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent impairment or damage

Report even if:

- you're not certain the product caused the event
- you don't have all the details

Report product problems – quality, performance or safety concerns such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labeling

How to report:

- just fill in the sections that apply to your report
- use section C for all products except medical devices
- attach additional blank pages if needed
- use a separate form for each patient
- report either to FDA or the manufacturer (or both)

Important numbers:

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-7737 to report by modem
- 1-800-FDA-1088 for more information or to report quality problems
- 1-800-822-7967 for a VAERS form for vaccines

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity may be shared with the manufacturer unless requested otherwise. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

FDA Form 3500-back **Please Use Address Provided Below – Just Fold In Thirds, Tape and Mail**

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Rockville, MD 20857

Official Business
Penalty for Private Use $300

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES OR APO/FPO

BUSINESS REPLY MAIL
FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE, MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

MEDWATCH
The FDA Medical Products Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787

RECEIVED
CLINICAL RESEARCH
REVIEW/OSN HFS-452

000002

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION

COMPLAINT / INJURY REPORT

1. COMPLAINT NUMBER: ~~NYK-3416~~ NYK-3416

2. DATE OF COMPLAINT (Month / Day / Year): 3/3/98

3. FORM OF COMPLAINT
a.
(1) ☐ TELEPHONE
(2) ☒ LETTER
(3) ☐ VISIT

4. SOURCE OF COMPLAINT
a.
(1) ☐ CONSUMER (3) ☐ TRADE SOURCE
(2) ☐ GOVERNMENT (4) ☒ OTHER
☐ L ☐ S ☐ F (Indicate in Remarks)

5. COMPLAINANT IDENTIFICATION
a. NAME AND ADDRESS (Include ZIP Code)
MEDWATCH FORM RECEIVED BY CFSAN, HFS_635
REPORTER: [redacted]

b. AREA CODE AND TELEPHONE NUMBER
HOME ( ) [redacted]
WORK ( )

6. COMPLAINT OR INJURY
a. DESCRIPTION OF COMPLAINT / INJURY

Attached medwatch received via fax today from CFSAn, Project #12713
to be completed by April 3, 1997 (CFSAN deadline date).
Please obtain (1) MEDICAL RECORDS
(2) COPY OF LABEL ONLY (no CR)
(3) ADVERSE REACTION QUESTIONNAIRE
to be completed by patient (if same as reporter)

b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT?
(1) ☒ NO (2) ☐ YES
(If "Yes" Explain in Remarks)

7. INJURY OR ILLNESS RESULTED
(1) ☐ NO
(2) ☒ YES *
*(If "yes" complete items a through d)

a. EIB (HFC - 161) NOTIFIED
(1) ☐ NO
(2) ☒ YES
DATE: 3/4/98

b. TYPE SYMPTOMS — ONSET (HR.)
(1) ☐ VOMITING
(2) ☐ NAUSEA
(3) ☐ DIARRHEA
(4) ☐ FEVER
(5) ☐ SKIN/EYE IRR.
(6) ☐ HEADACHE
(7) ☒ OTHER
STROKE of 64 yr old female, 230 lbs. prior TIP/high blood pressure and on medciation for same.

c. ATTENDING HEALTH PROFESSIONAL?
(1) ☐ NO (2) ☒ YES
(If "Yes" give name, address, and phone number)
TO BE OBTAINED: Dr. [redacted]

d. HOSPITALIZATION REQUIRED?
(1) ☐ NO (2) ☒ YES
(If "Yes" give name, address, phone number and dates)
11/26/97 [redacted]
TO BE OBTAINED: [redacted]

8. PRODUCT AND LABELING
a. BRAND NAME: FIT AMERICA
b. PRODUCT NAME: NATURAL WEIGHT CONTROL AID (EPHEDRINE Herb)
c. SIZE AND PACKAGE TYPE: capsules
d. NAME AND LOCATION OF STORE WHERE PURCHASED: Fit America Inc. Deerfield Beach FLA, 33441
e. PACKAGE CODE / SERIAL NUMBER / ETC.: 251702
EXP. / USE BY DATE: 09/99
f. DATE PURCHASED: not known
g. PRODUCT USED (If "Yes" enter date) (1) ☐ NO (2) ☒ YES Date: 9/97to 11/26/97
h. AMT. REMAINING: Several Capsules

9. MANUFACTURER / DISTRIBUTOR OF PRODUCT
a. HOME DISTRICT: FLA
b. C.F. NO.: NOCF
c. NAME AND LOCATION OF FIRM (Include ZIP Code)
FiT America Inc.
Deerfield Beach FL 33441
d. IMPORT PRODUCT
(1) ☐ NO
(2) ☐ YES (NOT Known)

10. EVALUATION AND DISPOSITION
a. PROBLEM KEY WORD
(1) CODE: RX
(2) DESCRIPTION: Stroke

b. EVALUATION
(1) ☐ NOT AN FDA OBLIGATION
(2) ☐ OBLIGATION, NO VIOLATION
(3) ☒ FDA ACTION INDICATED
(4) ☐ INSUFFICIENT INFORMATION UNABLE TO EVALUATE

b. DISPOSITION
(1) ☐ IMMEDIATE FOLLOW-UP
(2) ☐ F / U NEXT EI
(3) ☐ CLOSED WITHOUT FURTHER INVESTIGATION
(4) ☐ REFERRED TO OTHER FEDERAL AGENCY (Closes File)
(5) ☐ REFERRED TO STATE / LOCAL AGENCY (Closes File)
(6) ☒ REFERRED TO OTHER FDA _____ DISTRICT
(7) ☐ REFERRED TO OCI

11. PRODUCT CODE: 60CB E 03

12. INFORMATION COPIES TO:
☐ HFM-660 ☐ HFZ-343
☐ HFD-730 ☒ HFC-161
☐ HFV-210 ☒ HFS-635
☒ OTHER [redacted]

13. REMARKS
All records (originals) to be sent FEDEX to Bridgette Wallace, HFS-636 FDA/CFSAN, ~~2900~~ 200 C Street, S.W., Wash. D.C. 20204 (Room: 5019)

Please forwarded a copy of all records to me and I will distribute a set to DEIO/FLA-DO as well as NYK-DO Complaint file.

14. NAME AND TITLE OF DISPOSITION OFFICIAL
Marlene H. Doherty, CSI/CCC

15. DATE
3/4/98

000003

FORM FDA 2516 (1/96)

85

★ U.S. GPO 1997-521-557/85348

COMPLAINT / INJURY FOLLOW-UP

1. COMPLAINT NUMBER: NYK-3416

2.a. ACTION REQUESTED
(1) ☒ INVESTIGATION
(2) ☐ COLLECT SAMPLE
(3) ☐ INSPECTION
(4) ☐ OTHER:

2.b. REMARKS (*Additional details*): Adverse Event Report Project # 12713

2.c. REQUESTING OFFICIAL'S NAME AND TITLE: Bridgette Wallace (ARMS) Monitor

2.d. DATE REQUESTED: 3/3/98

2.e. PRODUCT NAME: Fit America Caps.

3.a. ASSIGNED TO: Joseph Maselli

3.b. DUE BY: ASAP

4.a. ACTION TAKEN
(1) ☒ INVESTIGATION
(2) ☐ SAMPLE COLLECTED
(3) ☐ INSPECTION
(4) ☐ NONE

4.b. SAMPLE NUMBER(s): n/a

4.c. DESCRIPTION OF ACTION TAKEN

On 3/20/98, the investigator visited the daughter of the complainant, [redacted], located at: [redacted] Ms. [redacted] is the reporter of the FDA Med-Watch form on behalf of her mother.

During this interview, limited information was obtained in view of the fact that Mrs. [redacted] the complainant, currently living with her husband, [redacted] in [redacted] According to Ms. [redacted], [redacted] is presenly receiving medical re-hab. at [redacted] All product labeling remains in the possession of Mr. [redacted] The complainant's initial medical care facility (emergency care) is located in [redacted] Attending physician is Dr. [redacted] was admitted to [redacted] on 11/26/97 with a diagnosis of Embolic Hemorrhage Stroke. According to Mrs. [redacted], [redacted] has responded to medical ~~treatment~~ treatment and care that was provided to her.

Ms. [redacted] provided the investigator with a signed medical release form, and the Adverse Reaction Questionnaire. They are attached.

4.d. ACTION OFFICIAL'S NAME AND TITLE: Joseph Maselli, Investigator

4.e. ACTION DISTRICT: NYK-DO

4.f. DATE COMPLETED: 3/23/98

5. MANUFACTURER / DISTRIBUTOR / DEALER RESPONSIBLE

5.a. HOME DIST.: FLA-DO

5.b. CF NO.: nocfn

5.c. NAME AND ADDRESS: Fit America Inc., Deerfield Beach, Fla. 33441

6. PROGRAM DATA

6.a. OPERATION: 13

6.b. PAC: 21008

6.c. PRODUCT CODE: 60CBE03

6.d EMP. HOME DIST.: NYK-DO

6.e. EMP. NO.: 111

6.f. POS CL.: 2

6.g. HOURS: 6

7. EVALUATION
(0) ☐ PENDING
(1) ☐ NO ACTION INDICATED (NAI)
(2) ☐ VOLUNTARY ACTION INDICATED (VAI)
(3) ☐ OFFICIAL ACTION INDICATED (OAI)
(4) ☐ NOT AN FDA OBLIGATION
(5) ☐ REFERRED TO HOME DISTRICT
(6) ☐ INSUFFICIENT INFO. UNABLE TO EVAL.
(7) ☐ REFERRED TO OCI

8. FINAL DISPOSITION
(1) ☐ FOLLOW-UP NEXT E1
(2) ☐ WARNING LETTER
(3) ☐ CITATION
(4) ☐ SEIZURE
(5) ☐ INJUNCTION / PROSECUTION
(6) ☐ REFERRED TO OTHER AGENCY
(Indicate Agency in **Remarks***)*
(7) ☐ RECALL
(8) ☐ NO ACTION

9. INFO. COPIES TO:
☐ HFB-100
☐ HFD-730
☐ HFV-236
☐ HFZ-343
☐ HFC-161
☐ HFS-635
☐ _____
☐ _____
☐ _____
☐ _____
☐ _____
☐ _____
☐ _____

REMARKS

000004

NAME AND TITLE OF DISPOSITION OFFICIAL	DISPOSITION	DISPOSITION DATE

FORM FDA 2516a (3/94)

★ U.S. GPO: 1995-386-960/20706

Adverse Reaction Questionnaire

Complaint Number: NYK-3416 Investigator: Joseph MASCILI

Consumer Information

Date of Report: 3/20/98 MM/DD/YY reported by

Initial Report Source: ☐ORA Consumer Injury
☐Telephone ☐Correspondence ☑MedWatch
☐USP ☐PQRS ☐Poison Control ☐CDC

Name: [redacted] Gender: ☐F ☐M Age: 64

Race: ☑1-White ☐2-Black ☐3-Asian/Pacific Islander ☐4-Native American ☐5-Hispanic
☐8-Other _____ ☐9-Unknown

Information on Adverse Reaction

Date of Adverse Reaction: 11/26/97
Previous Reaction to Product Type: ☐Yes ☐No

Give the site of consumption/ingestion (e.g. home, restaurant, office): residence [redacted]

The following information relates to the consumers' use of the product.

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms):
stroke in Evening, appx. 3-4 hrs. after taking product.

How long did the symptoms last? Admitted to hospital, icu for appx. 2 days.

Give the circumstances of exposure (i.e. how much was taken, how was the product taken and how often was it taken, etc.).
up to 5 capsules a day, each 470 mg. by mouth.

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event:
Aznacine 2 Tbs x 5 mg. daily
Propranolol 80 mg. daily, 1 Aspirin daily

Did event abate after use of suspected product stopped or dose reduced: ☐Yes ☑No ☐Unknown
Did symptoms reoccur after reintroduction of suspected product: ☐Yes ☐No ☐Unknown ☑Not Applicable
Did symptoms reoccur after using other products with the same ingredients: ☐Yes ☐No ☐Unknown ☑Not Applicable

Medical Information

Was a health care provider seen?: ☑Yes ☐No
Give health care provider's name, address and telephone number: [redacted]

Occupation of Health Care Provider: ☑MD ☐Osteopath ☐Naturopath ☐Nurse ☐Pharmacist
☐Other (specify) _____

What medical tests were performed and what were the results? CAT SCAN, Admitted icu

What was the medical diagnosis? embolic hemorrhage stroke

What treatment(s) was given (e.g., drugs, other)?
Heparin 2x days, Coumadin few days after (Coumadin?)

Were there any preexisting condition(s)/treatment(s)? controlled blood pressure
(If YES, list them including allergies, and chronic diseases): ☐Yes ☐No TIA year previous

000005

Product Category

MJF-3416

1. Adverse reaction to:
   - ☐ Medical Food (under medical supervision) ☐ Infant Formula
   - ☒ Dietary Supplement (a vitamin, an essential mineral, a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe, amino acids, extracts from animal glands, garlic extract; fish oils; oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin, and mixtures of these ingredients.)
   - ☐ Other (traditional food) _____

Other Product Problems

2. ☐ Foreign Object (specify): _____
3. ☐ Other (specify): _____

Information on Suspected/Alleged Product

Give the product name as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label): Fit America Natural Weight Control Aid. 470 mg each capsules., Deerfield Beach, FLA 33441

lot # 251702

Exp. 09/99

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):

☐ Check here if ingredients are unknown

Ephedrine

~~Asian~~ MA Huang

If a particular ingredient is suspected of contributing to the reaction, please indicate the appropriate category below:

- ☐ Aspartame
- ☐ Monosodium Glutamate
- ☐ Sulfite
- ☐ ~~Other~~ Ephedrine – MA Huang
- ☐ Unknown
- ☐ Color Additive (please specify) _____

Is the product label available, if yes submit a quality copy along with this questionnaire: ☐ Yes ☒ No ☐ Unknown

Product Sample Available: ☐ Yes ☐ No ☐ Unknown

Outcome Attributed to Adverse Event:

(If yes, include pertinent medical records)

Death: ☐ Yes ☒ No

Life-Threatening: ☒ Yes ☐ No

Hospitalization: ☒ Yes ☐ No (if YES, indicate if initial or prolonged) (1 cm) Admit 11/26/97 to 12/4/97 sick.

Required intervention to prevent permanent impairment/damage: ☒ Yes ☐ No

Did the adverse reaction result in a congenital anomaly: ☐ Yes ☒ No

tTO: Lori Love, M.D., Ph.D

FROM: Constance J. Hardy CJH

DATE: 6/22/99

SUBJECT: ARMS 12713—Additional Followup--Consumer Usage of Product/Signs and Symptoms Prior to Stroke

I spoke to Ms. [redacted] on 6/22/99 in an attempt to clarify her use of the product (Fit America Weight Control Aid) prior to her stroke on 11-26-97. Information in the adverse event questionnaire and the MedWatch form stated that she took "up to 5 capsules/d" from 9/97 – 11/26/97, but did not mention the dosing frequency.

Unfortunately because of her stroke and with the passage of time, Ms. [redacted] stated that she could not remember exactly what the product directions[1] were, or exactly how many capsules she took on a typical day. She definitely stated that she never took 5 capsules at the same time.

When asked whether she had any symptoms prior to her stroke, she stated that there were none, and that the stroke was sudden.

File: c:[redacted]/ephedrafu/fu12713.doc

[1] The product directions state "Take capsules with 8 oz (240) ml water 1 hour before meals. Commence with low dose (one or two capsules per day) for 2-4 days, and then gradually build up to the most comfortable dosage level. Do not take more than one capsule every 4 hours, or exceed a maximum of 5 capsules per day...":

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration

[redacted]

DATE: 5/11/98

TO: Keith S. Ehrlich, SI

FROM: Angela K. Rhodes, CSO

SUBJECT: F/U to CFSAN AE #12713, Complaint NYK-3416 per FLA-DO memo dated 4/2/98.

[redacted]

On 4/23/98, I contacted the medical records department, at [redacted] in [redacted], in order to obtain medical records for [redacted] as instructed in the 4/2/98 FLA-DO assignment memo. I spoke with [redacted] whom informed me that, as a government agency, a medical records release was not required from the patient in order to get copies of medical records. I faxed Ms. [redacted] a written request for records. **(att: 1)** These records were received and are attached. **(ex: 1)**

Due to the fact that medical records release authorization was not needed, a visit to the home of [redacted] was unnecessary. However, upon the advice of the CFSAN ARMS monitor, medical records release authorization forms were sent to Ms. [redacted] for her signature. **(att: 2)** Ms. [redacted] signed these release forms and returned them to [redacted] per my request. **(att: 3)** Ms. [redacted] also provided unopened bottles of the Fit America product in question. Labeling and a product insert were obtained from these bottles and are attached.

TO: Phil Delisle
FLA-DO Complaint Coordinator

MAY 12 1998

The above investigator's memo reports follow-up with the subject complainant. Medical records and labeling were obtained as requested. A copy of brochures containing smoking cessation products is being forwarded to the OTC Compliance Branch for informational purposes. No further follow-up is planned by [redacted].

Keith S. Ehrlich
Supervisory Investigator

RECEIVED
MAY 29 1998

O+att/ex: PRD
cc+att/ex: FLA-DO/EF
cc+att/ex: [redacted]EF
cc+ex#3: HFD-312/Budich
cc: KSE

000008

(ex: 2) Product was field destroyed. Ms. [redacted] also provided promotional literature associated with the Fit America product. **(ex: 3)** [redacted] Ms. [redacted] husband, confirmed that the unopened product bottles provided to the FDA were the same lot number and product as that opened and used by his wife prior to her stroke.

Through discussions held on 4/20,23,24/98, it was determined that Ms. [redacted] description of events does not differ from information previously provided to NYK-DO. Therefore, an additional "Adverse Reaction Questionnaire" was not completed.

Promotional literature provided by Mrs. [redacted] includes information on a smoking cessation product, Nico-Fit. **(ex: 3)** A discussion with Kevin Budich, OTC Compliance Branch, indicates that information is currently being collected concerning smoking cessation products using herbs and nutritional supplements. Mr. Budich requested that promotional literature be forwarded to him.

ATTACHMENTS:

1 - FDA letter dated 4/24/98 to [redacted]
2 - Signed FDA Form 461, Authorization for Medical Records Disclosure
3 - FDA letter dated 4/24/98 to [redacted]

EXHIBITS:

1 - Medical Records
2 - Product Labeling
3 - Promotional literature

Angela K. Rhodes
Angela K. Rhodes
Investigator, [redacted]